Subject: Talc/Asbestos

Summary of FDA Meeting, 8/11/72

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Memo to File

Dr. Schaffner opened the meeting by saying this meeting was asked for by companies and CTFA to discuss technical methods of assay of asbestos in talc with Dr. Lewin, the objective being a satisfactory method for inclusion in an FDA policy statement in the Federal Register accompanied by a publication of the results of the survey of 102 non-regulatory samples obtained last winter and early spring. He said that FDA has not officially accepted the report and does not intend to disclose it to anyone until "we are ready."

Mr. Merritt: It is unfair to select samples at random and release information by brand name. This is not an industry survey, but an industry sampling. If the results are in error, the FDA will have to apologize later. Also, the release of the information will cause economic hardships. He suggested that if FDA releases anything, it should be by code number.

Dr. Schaffner: Our lawyers say we must release the actual names since the report included at the end a code list with the actual tradenames.

Mr. Merritt: This is not legally the case. We reserve the right to legal action by CTFA.

Dr. Schaffner: Maybe an informal meeting between CTFA and FDA lawyers should be arranged.

Mr. Merritt: FDA is penalizing voluntary compliance. This is like a police state.

Dr. Schaffner: We follow FDA policy.

Mr. Merritt: The regulations on Freedom of Information are not final yet.

Dr. Lewin: My results may be unfair to some companies since in some cases I had 3 containers with differing results from one company vs. 1 container from another.
The meeting was then turned over to Dr. Burdick (CTFA spokesman). Dr. Burdick suggested that Dr. Lewin review his findings.

**Dr. Lewin:** I prepared for the review by first studying commercial talcs provided by Whittaker, Clarke, & Daniels - samples from Korea, Italy, U.S., Canada, India, China, France, and South America. I established the technique for determining chrysotile, tremolite, anthophyllite, and actinolite, also, accessory minerals, e.g., chlorite, thologopite, dolomite, quartz. Rarely we found kaolin.

To establish chrysotile, which has one X-ray peak close to chlorite, we used step scanning.

We also used DTA to confirm presence of tremolite as well as electron microscopy.

**Dr. Nashed:** DTA confirms tremolite. How about chrysotile?

**Dr. Lewin:** DTA is less sensitive here.

**Dr. Burdick:** Did you carry out these confirmatory procedures on all positive samples.

**Dr. Lewin:** No, but if asbestos result is more than 2%, there is no question that it is present. You can see it by light microscopy.

**Dr. Burdick:** Johnson & Johnson has carried out some tests on their SHOWER TO SHOWER.

**Dr. Lewin:** Knowing Johnson & Johnson, I repeated my work on SHOWER TO SHOWER last night using step scanning. I find that my initial result is confirmed.

**Dr. Burdick:** Perhaps Dr. Nashed will give us a report.

**Dr. Nashed:** When we were contacted by Dr. Schaffner, we were told that our sample lot 5507BG contained 5% chrysotile. We were quite puzzled since we had examined Italian talc and SHOWER TO SHOWER and found no asbestos. We determined that 5507BG is a label control number used on labels of the product from February 1970 to August 1971, and rather than delay our tests to get the actual lot number, we sampled production from that period from Quality Assurance retained samples. We selected at random 15 samples representing each month
of production. The samples were tested by Johnson & Johnson and McCrone Associates. The tests included electron microscopy, electron diffraction, and X-ray scanning, step scanning, powder camera techniques, and petrographic examination as well as sieve analyses. We found no chrysotile. We also examined the sample kindly provided us by Dr. Lewin with a similar finding. Our reference sample from the same lot was found to be equal to Dr. Lewin's sample, both showing no chrysotile.

We also had had the Italian mine samples tested by Professor Pooley who found no asbestos.

These results show the need to confirm Dr. Lewin's results by electron microscopy and electron diffraction.

Dr. Ian Stewart will discuss his findings in detail.

**Dr. Stewart:** Dr. Stewart presented a detailed review of his X-ray and EM findings. Dr. Lewin disagreed with his interpretation of the X-ray data and a long technical discussion ensued without any agreement. It included a comment by Dr. Weissler that the EM sample is too small and may not show fibers. We later said that the number of fibers in 1 gm. chrysotile is enormous and should be seen.

The meeting adjourned for lunch.

During lunch, I discussed with Dr. Lewin the fact that no fibers can be seen by EM and if indeed the sample contained 5% chrysotile, we should have seen it. I reminded him of Dr. Langer's ability to see traces of asbestos by that method. He agreed that this is puzzling. I suggested that he should look at our sample by EM. He said that chrysotile may not be seen because it may be growing inside the talc platelets(??) which is a hypothetical point. He said to resolve this may be a doctoral dissertation.

The meeting was reconvened at 1:30 pm.

**Dr. Burdick:** We should defer the discussion of X-ray technique since it does not appear to be easily resolvable. The point is confirmatory tests are needed. I suggest that Dr. Lewin do them.

**Dr. Nashed:** As a matter of fact, Dr. Lewin, based on our discussion during lunch, you would want to look at our sample by electron microscopy.
Dr. Schaffner: We should not research this matter forever. Time is running out; we have to respond to consumerists and we have to control asbestos in talc. Can these tests be completed in a short time?

Dr. Sprott (Avon): The tests should be repeated on fresh samples since some of the samples in the report are old, before the question on asbestos was raised.

Dr. Schaffner: I understand that talc can be purified to remove asbestos (looking at Noshed).

Mr. Roesch (WCD): This cannot be done. The mine must be substantially free of asbestos.

Dr. Sprott (Avon): We do not know if our supply has <1% asbestos.

Dr. Lewin: I suggest that in order to save time, I only do 7 samples which had shown high tremolite or chrysotile.

Dr. Schaffner: No. I think all samples must be confirmed.

A discussion of the merits of DTA, also electron microscopy (suggested by Ian Stewart, who also estimated $100-300 per sample) and light microscopy ensued. Dr. Lewin finally suggested that the samples be examined by light microscopy and if the asbestos is not seen, the sample will be declared "no detectable asbestos" notwithstanding the X-ray finding.

Dr. Stewart: The light microscopy is not capable of detecting fine chrysotile fibers.

Dr. Weissler (FDA): I understand that some samples will be passed even though they contain such fibers, but we are willing to live with it.

Dr. Schaffner: The policy will depend on X-ray which is sensitive to more than 1% asbestos. Does anybody object from a toxicological point of view to this?

No objections.

Dr. Schaffner: (to Dr. Lewin): How long do you estimate it will take to complete light microscopy confirmatory tests?

Dr. Lewin: Should be complete by October 1.
Dr. Goudie (to Dr. Schaffner): Would it be all right for our consultant, Mr. Stewart, to discuss independently the question of X-ray interpretation with Dr. Lewin?

Dr. Schaffner: It is up to Dr. Lewin.

Dr. Lewin: I have no objections. I will also release my notes on procedure to interested parties.

The meeting adjourned.

Later, I suggested to Mr. Merritt that CTFA conduct a parallel survey on fresh samples since obviously the report will result in confirmation of asbestos in many of the old production samples. Mr. Merritt said that this is indicated.

WN/cw

W. Nashed

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